AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1-90. (Canceled)

91. (Withdrawn) A method of producing a fast-dispersing, non-compressed solid and stable dosage form having low friability, comprising at least one matrix forming agent and being suitable for oromucosal administration comprising an effective dose for desensitizing an individual to at least one allergen, comprising the steps of:

(a) preparing an aqueous solution comprising said at least one allergen and said at least one matrix forming agent,

(b) introducing the solution into one or more depressions in a mould

(c) subjecting the loaded mould to freezing and freeze-drying using standard conditions of shelf temperature and chamber pressure to obtain said solid dosage form in each depression.

92. (Withdrawn) A method according to claim 91 wherein step (b) comprises introducing the solution into depressions in a multilayer laminated blister sheet.

93. (Withdrawn-Currently Amended) A method of measuring the friability of a solid dosage form ~~as defined in claim 1~~ comprising the following steps:

(a) placing individual sealed blisters each containing a solid dosage form in equipment suitable for friability measurements;

(b) moving the sealed blister containing the solid dosage form for an appropriate time and at an appropriate velocity;

(c) removing the sealed blister containing the solid dosage form ;

(d) opening the blister and placing the solid dosage form and any residues in a container;

(e) removing the solid dosage form from the container leaving any loose residuals in said container;

(f) performing an allergen specific assay on said residues determining the allergen content in said residues; and optionally calculating the percentage allergen content in said residues of the total allergen content of the solid dosage form unit,

wherein the solid dosage form is a fast-dispersing, non-compressed solid dosage form suitable for oromucosal administration comprising:

(a) a matrix formed from at least one matrix-forming agent, and

(b) an effective dose of an allergen for desensitizing an individual to said allergen, wherein

(c) the loss of the allergen content in said dosage form is less than 50% of the initial allergen content after being held for 3 months at 25°C and 60% relative humidity, and

(d) the loss of allergen content from said solid dosage form is less than about 0.5 µg allergen extract or less than about 0.05 µg major allergen when subjected to a friability test.

94. (Withdrawn) A method according to claim 93 wherein:

(a) between 1 and 100 blisters containing the solid dosage form are used,

(b) an equipment for friability measurements as described in European Pharmacopoeia V.2.9.7 is used,

(c) the solid dosage forms are rotated for 100 turns at 25 ± 1 rpm, and

(d) the allergen specific assay is an immunochemical allergen specific assay.

95. (Withdrawn) A method according to claim 94 wherein the immunochemical assay is an enzyme-linked immunosorbant assay.

96. (Canceled)

97. (Original) A kit for treatment of allergy or for alleviating allergy symptoms comprising:

(a) a plurality of solid oral dosage forms in a sealed container, each of said solid oral dosage forms being held in a sealed enclosure and comprising an effective amount of an allergen suitable for oromucosal administration; and

(b) each of said solid dosage forms containing the same amount of the allergen.

98. (Original) A kit according to claim 97 further comprising instructions for using the multiple solid dosage forms.

99. (Original) A kit according to claim 97, wherein the dosage form is a fast-dispersing dosage form.

100. (Original) A kit according to claim 97, wherein each of the solid dosage forms are located in individually sealed blisters in a multiple blister pack.

101. (Original) A kit according to claim 97, wherein the solid dosage forms comprise gelatine.

102. (Original) A kit according to claim 101, wherein the solid dosage forms further comprise mannitol.

103. (Original) A kit according to claim 101, wherein the gelatine is fish gelatine.

104. (Original) A kit according to claim 97, wherein the effective amount of allergen is between about 2.5 μg – about 3.75 mg extract /solid dosage form.

105. (Withdrawn) A method for treating a mammal patient afflicted with allergy, comprising:

(a) providing a kit according to claim 97, and

(b) repeatedly administering to said human at least one of said solid dosage forms from the kit until the allergy symptoms are relieved, wherein the repeated administration lacks an updosing step.

106-129. (Canceled)

130. (Currently Amended) A multiple dose set of pharmaceutical products suitable for oromucosal administration to a mammal, said products being fast-dispersing solid dosage forms comprising:

a matrix suitable for fast-dispersion upon oromucosal administration; and

2.5 μg to about 75 μg of a major grass pollen allergen selected from the group consisting of grass group 1 allergen, grass group 2/3 allergen, grass group 5 allergen and grass group 6 allergen

~~according to claim 122~~, each dose containing the same amount of allergen.

131. (Currently Amended) A multiple dose set of pharmaceutical products suitable for oromucosal administration to a mammal, said products being fast-dispersing solid dosage forms comprising:

a matrix suitable for fast-dispersion upon oromucosal administration; and

an allergen in an amount sufficient to induce an allergen specific immune response to said allergen in said mammal

~~according to claim 110~~, each dose containing the same amount of allergen.

132. (Withdrawn) A method for inducing an allergen specific immune response in a mammal, comprising oromucosal administration of a fast-dispersing solid pharmaceutical product that comprises:

a matrix suitable for fast-dispersion upon oromucosal administration; and

an allergen in an amount sufficient to induce an allergen specific immune response to said allergen in said mammal, wherein said pharmaceutical product is provided in its own separate container or compartment.

133. (Withdrawn) The method of claim 132 wherein said allergen comprises an allergen extract.

134. (Withdrawn) The method of claim 132 wherein said allergen comprises a recombinant allergen.

135. (Withdrawn) The method of claim 132 comprising oromucosal administration of a plurality of said pharmaceutical products.

136. (Withdrawn) The method of claim 132 wherein the product has a potency of about 65 to about 17,600 Biological Allergen Units (BAU).

137. (Withdrawn) The method of claim 132 wherein the product has a potency of about 650 to about 3,500 Biological Allergen Units (BAU).

138. (Withdrawn) The method of claim 133 wherein the allergen comprises from about 2.5 μg to about 3.75 mg of allergen extract.

139. (Withdrawn) The method of claim 133 wherein the allergen comprises from about 25 μg to about 0.75 mg of allergen extract.

140. (Withdrawn) The method of claim 132 wherein the allergen comprises a major allergen in an amount from about 0.25 μg to about 375 μg.

141. (Withdrawn) The method of claim 132 wherein the allergen comprises a major allergen in an amount from about 2.5 μg to about 75 μg.

142. (Withdrawn) The method of claim 132 wherein the allergen comprises a major grass pollen allergen.

143. (Withdrawn) The method of claim 142 wherein the major grass pollen allergen is a member selected from the group consisting of group 1 allergen, group 5 allergen and group 6 allergen.

144. (Withdrawn) The method of claim 132 wherein the product is in a solid, non-compressed form.

145. (Withdrawn) The method of claim 132 wherein the product further comprises at least one anti-allergic drug.

146. (Withdrawn) The method of claim 132 further comprising providing instructions concerning use of the product.

147. (Withdrawn) The method of claim 132 which comprises treating said mammal to alleviate allergenic symptoms.

148. (Withdrawn) The method of claim 132 which comprises treating said mammal to prophylactically protect said mammal.

149. (Withdrawn) The method of claim 122 which comprises treating said mammal to desensitize said mammal to said allergen.

150. (Withdrawn) A method of preparing a solid, non-compressed pharmaceutical product for oromucosal administration of an allergen sufficient to induce an allergen-specific immune response in a mammal, the method comprising the steps of:

combining a matrix material with an allergen in a liquid solution; and

removing the liquid to form the non-compressed pharmaceutical product,

wherein the pharmaceutical product has a potency of from about 65 to about 17,600 Biological Allergen Units (BAU).

151. (Withdrawn) A method of preparing a solid, non-compressed pharmaceutical product for oromucosal administration of an allergen sufficient to induce an allergen specific immune response in a mammal, the method comprising the steps of:

combining a matrix material with an allergen in a liquid solution; and

removing the liquid to form the non-compressed pharmaceutical product,

wherein the pharmaceutical product comprises from about 2.5 μg to about 3.75 mg allergen extract.

152. (Withdrawn) A method of preparing a solid, non-compressed pharmaceutical product for oromucosal administration of an allergen sufficient to induce an allergen specific immune response in a mammal, the method comprising the steps of:

combining a matrix material with an allergen in a liquid solution; and

removing the liquid to form the non-compressed pharmaceutical product,

wherein the pharmaceutical product comprises from about 0.25 μg to about 375 μg major allergen.

153. (Withdrawn) The method of claim 150 further comprising the step of adding a compound to affect the pH of said liquid solution.

154. (Withdrawn) The method of claim 153 wherein the step of adding a compound to affect pH comprises adding sodium hydroxide to adjust or maintain the pH of said liquid solution within a range of pH 6.5 to 9.

155. (Withdrawn) The method of claim 150 wherein the product has a potency of about 650 to about 3,500 Biological Allergen Units (BAU).

156. (Withdrawn) The method of claim 150 wherein the pharmaceutical product is free of an added compound that functions as an adjuvant when the product is administered to the mammal.

157. (Withdrawn) The method of claim 150 wherein the allergen comprises a major grass pollen allergen.

158. (Withdrawn) The method of claim 150 wherein the solid, non-compressed pharmaceutical product is not coated.

159. (Withdrawn) The method of claim 150 wherein the matrix comprises non-bovine gelatin.

160. (Withdrawn) The method of claim 150 wherein the matrix comprises non-mammalian gelatin.

161. (Withdrawn) The method of claim 150 wherein the matrix comprises fish gelatin.

162. (Withdrawn) The method of claim 150 wherein the pharmaceutical product further comprises an anti-allergic drug.

163. (Withdrawn) A method for inducing an allergen specific immune response in a mammal comprising administering oromucosally to the mammal a fast dispersing product having a potency of about 65 to about 17,600 Biological Allergen Units (BAU).

164. (Withdrawn) The method of claim 163 wherein the fast dispersing product is in a solid, non-compressed form.

165. (Withdrawn) The method of claim 163 wherein the fast dispersing product is free of an additive that functions as an adjuvant when the product is administered to the mammal.

166. (Withdrawn) The method of claim 163 wherein the potency of said allergen is from about 650 to about 3,500 Biological Allergen Units (BAU).

167. (Withdrawn) The method of claim 163 wherein the product comprises a major grass pollen allergen.

168. (Withdrawn) The method of claim 163 wherein the product comprises a non-mammalian gelatin.

169. (Withdrawn) A method for desensitizing a mammal to a major allergen or major allergens, comprising administering oromucosally to a mammal in need thereof a plurality of fast dispersing pharmaceutical products, each pharmaceutical product comprising substantially the same amount of at least one major allergen, wherein said amount is sufficient to induce an allergen specific immune response to said major allergen(s) in said mammal, and wherein each pharmaceutical product in the plurality is administered according to a schedule of treatment.

170. (Withdrawn) A method for desensitizing a mammal to an allergen or allergens, comprising administering oromucosally to a mammal in need thereof a plurality of fast dispersing

pharmaceutical products, each pharmaceutical product comprising substantially the same amount of an allergen extract, which is sufficient to induce an allergen specific immune response to at least one major allergen in said allergen extract in said mammal, and wherein each pharmaceutical product in the plurality is administered according to a schedule of treatment.

171. (Withdrawn) The method of claim 169 wherein the product has a potency of about 65 to about 17,600 Biological Allergen Units (BAU).

172. (Withdrawn) The method of claim 170 wherein the product comprises from about 2.5 μg to about 3.75 mg allergen extract.

173. (Withdrawn) The method of claim 171 wherein the product has a potency of about 650 to about 3,500 Biological Allergen Units (BAU).

174. (Withdrawn) The method of claim 169 wherein the pharmaceutical products are substantially free of an additive that functions as an adjuvant when said products are administered to the mammal.

175. (Withdrawn) The method of claim 169 wherein the at least one major allergen is a major grass pollen allergen.

176. (Withdrawn) The method of claim 169 wherein the product is in a non-compressed form and the product is not coated.

177. (Withdrawn) The method of claim 169 wherein the product comprises non-bovine gelatin.

178. (Withdrawn) The method of claim 169 wherein the product comprises non-mammalian gelatin.

179. (Withdrawn) The method of claim 169 wherein the product comprises fish gelatin.

180. (Withdrawn) The method of claim 169 wherein the product further comprises an anti-allergic drug.

181-182. (Canceled)

183. (Withdrawn) A method for treating grass pollen allergy in a mammal which comprises:

orally administering to said mammal an oral dosage form containing a predetermined effective dose of a major grass pollen allergen for desensitization of said mammal to grass pollen and

repeating the administration of the same predetermined effective dose at least once daily.

184. (Withdrawn) The method of claim 183 wherein said effective dose of said major grass pollen allergen has a potency of about 65 to about 17,600 BAU.

185. (Withdrawn-Currently Amended) The method of claim 184 wherein said major grass pollen allergen is a member selected from the group consisting of grass group 1 allergen, grass group 2/3 allergen, grass group 5 allergen and grass group 6 allergen.

186. (Withdrawn) The method of claim 185 wherein said dosage form comprises from about 2.5 μg to about 75 μg of said major grass pollen allergen.

187. (Withdrawn) The method of claim 184 wherein said dosage form comprises non-mammalian gelatin.

188. (Withdrawn) A method for treatment of an allergy which comprises:

orally administering to a mammal in need of such treatment an oral dosage form containing a predetermined effective dose of an allergen for desensitization to said allergy, and

repeatedly administering the same predetermined effective dose to said mammal.

189. (Withdrawn) The method of claim 188 wherein said administering step comprises administering said dosage form at least once per day.

190. (Withdrawn) The method of claim 189 wherein said dose has a potency of about 65 to about 17,600 Biological Allergen Units(BAU).

191. (Withdrawn) The method of claim 189 wherein said oral dosage form comprises non-mammalian gelatin.

192. (Withdrawn) The method of claim 190 which comprises continuing said daily administration until the symptoms of said allergy in said mammal are relieved.

193. (Previously Presented) A kit for use in treating an allergy in a mammal which comprises:

a solid support,

a plurality of solid oral dosage forms, each of said solid oral dosage forms being held in a sealed enclosure on said support and each containing essentially the same effective dose of at least one major allergen for desensitizing said mammal to said major allergen.

194. (Previously Presented) The kit of claim 193 wherein each of said oral dosage forms comprises non-mammalian gelatin.

195. (Previously Presented) The kit of claim 193 wherein said oral dosage forms has a potency of about 65 and about 17,600 BAU.

196. (Previously Presented) The kit of claim 193 wherein each of said oral dosage forms comprises between about 0.25 μg to about 375 μg of said major allergen.

197. (Previously Presented) The kit of claim 193 wherein the major allergen is a grass pollen allergen.

198. (Currently Amended) The kit of claim 197 wherein the grass pollen allergen comprises from about 0.25 μg to about 375 μg of a member selected from the group consisting of grass group 1 allergen, grass group 2/3 allergen, grass group 5 allergen and grass group 6 allergen.

199-202. (Canceled)

203. (Previously Presented) A kit according to claim 97 wherein the solid oral dosage forms disintegrate within about 60 seconds.

204. (Previously Presented) A kit according to claim 97 wherein the solid oral dosage forms disintegrate within about 30 seconds.

205. (Previously Presented) A kit according to claim 97 wherein the solid oral dosage forms disintegrate within about 10 seconds.

206-213. (Canceled)

214. (Previously Presented) A kit according to claim 193 wherein the solid oral dosage forms disintegrate within about 60 seconds.

215. (Previously Presented) A kit according to claim 193 wherein the solid oral dosage forms disintegrate within about 30 seconds.

216. (Previously Presented) A kit according to claim 193 wherein the solid oral dosage forms disintegrate within about 10 seconds.

217. (New) A kit according to claim 193, wherein each of the dosage forms are fast-dispersing dosage forms.

218. (New) A kit according to claim 194 , wherein each of the solid dosage forms further comprise mannitol.

219. (New) A kit according to claim 194, wherein the non-mammalian gelatin is fish gelatin.

220. (New) The kit of claim 97 wherein each of said oral dosage forms have a potency of between about 65 and about 17,600 BAU.

221. (New) The kit of claim 97 wherein each of said oral dosage forms comprises between about 0.25 μg to about 375 μg of said allergen.

222. (New) The kit of claim 97 wherein the allergen is a grass pollen allergen.

223. (New) The kit of claim 97 wherein said allergen comprises an allergen extract.

224. (New) The kit of claim 193 wherein said allergen comprises an allergen extract.

225. (New) The kit of claim 97 wherein said allergen comprises a recombinant allergen.

226. (New) The kit of claim 193 wherein said allergen comprises a recombinant allergen.

227. (New) The kit of claim 97 wherein each of the dosage forms have a potency of between about 650 to about 3,500 Biological Allergen Units (BAU).

228. (New) The kit of claim 193 wherein each of the dosage forms have a potency of between about 650 to about 3,500 Biological Allergen Units (BAU).

229. (New) The kit of claim 97 wherein each of the allergen comprises a major allergen in an amount from about 2.5 μg to about 75 μg.

230. (New) The kit of claim 193 wherein each of the allergen comprises a major allergen in an amount from about 2.5 μg to about 75 μg.

231. (New) The kit of claim 97 wherein each of the dosage forms is a solid, non-compressed form.

232. (New) The kit of claim 193 wherein each of the dosage forms is a solid, non-compressed form.

233. (New) The kit of claim 97 wherein each of the dosage forms further comprises at least one anti-allergic drug.

234. (New) The kit of claim 193 wherein each of the dosage forms further comprises at least one anti-allergic drug.

235. (New) The kit of claim 97 wherein each of the dosage forms are free of an added compound that functions as an adjuvant when the product is administered to the mammal.

236. (New) The kit of claim 193 wherein each of the dosage forms are free of an added compound that functions as an adjuvant when the product is administered to the mammal.

237. (New) The kit of claim 97 wherein each of the dosage forms is not coated.

238. (New) The kit of claim 193 wherein each of the dosage forms is not coated.

239. (New) The kit of claim 97 wherein each of the dosage forms has a water activity of between about 0.4 to about 0.5.

240. (New) The kit of claim 193 wherein each of the dosage forms has a water activity of between about 0.4 to about 0.5.

241. (New) The kit of claim 97 wherein each of the dosage forms has a water content of between about 2.0% to about 8.0% weight.

242. (New) The kit of claim 193 wherein each of the dosage forms has a water content of between about 2.0% to about 8.0% weight.

243. (New) The kit of claim 97 wherein the allergen is selected from the group consisting of grass pollen allergen, birch pollen allergen, tree pollen allergen, weed pollen allergen, herb pollen allergen, and ragweed pollen allergen.

244. (New) The kit of claim 193 wherein the allergen is selected from the group consisting of grass pollen allergen, birch pollen allergen, tree pollen allergen, weed pollen allergen, herb pollen allergen, and ragweed pollen allergen.